K003352

MAR 2 0 2001

PREMARKET NOTIFICATION
510(K) SUMMARY
(As Required by 21 CFR 807.92)

1. Submitter's Name: eScreen, Inc.
   Address: 5900 Wilshire Blvd 22nd Floor
   Los Angeles, CA 90036
   Telephone: 800.733.6676
   Contact Person: John Goodin
   Date Prepared: December 28, 2000

2. Device Name: eScreen Drugs of Abuse Screening System
   Proprietary Name: eScreen Drugs of Abuse Screening System
   Usual Name: eScreen Drugs of Abuse Screening System
   Classification Name: Drugs of Abuse Screening kits

3. Device(s) to which substantial Equivalence is claimed:

   Genie Cup™ Integrated Screening Device
   Forefront InstaCheck™ Multi-Drug Test Panels

4. Description of the Device:

The eScreen Drugs of Abuse Screening System includes the eCup and eReader. The eCup is the combination of a urine collection device and lid or cap. The lid or cap incorporates the use of a pipetting device and two in vitro diagnostic test strips. Each of the two test strips contains multiple EIA drugs of abuse tests. The eReader is designed exclusively to actuate the pipetting device and electronically "read" the test strips located on top of the eCup.

The eScreen Drugs of Abuse Screening System indicated for use by professionals in prescription workplace settings for the automated screening of drugs of abuse in human urine.

The eScreen Drugs of Abuse Screening System includes two test strips utilizing qualitative competitive inhibition immunoassay strip technology for the qualitative determination of the presence the following classes of drugs and their metabolites at the following cutoff concentrations:

Cocaine	300 ng/ml
Phencyclidine	25 ng/ml
Cannabinoids	50 ng/ml
Methamphetamine	1000 ng/ml
Morphine	2000 ng/ml

5. Substantial Equivalence

The eScreen system integrates the collection, storage and analysis of human urine and is intended for use by professionals for the rapid, qualitative detection of target drugs and/or metabolites, including cocaine, cannabinoids, methamphetamine, opiates, and phencyclidine, in urine. It is not intended for

over the counter sales to lay persons. The predicate devices similarly integrate the collection, storage and analysis of human urine and are intended for the qualitative determination of the presence of drugs of abuse and their metabolites followed by the use of an alternate analytical method, Gas Chromatography/Mass Spectroscopy ("GC/MS"), to confirm presumptively positive results. Thus, the eScreen system and the predicate devices have the same intended use and indications.

The eScreen system and predicate devices have similar principles of operation and technological characteristics. The eScreen system and the predicate devices employ membrane strips that have been pre-coated with drug-protein conjugates in separate test bands or zones. Human urine specimens react with the test reagents and migrate across the test membrane, resulting in visible bands with each drug/metabolite of interest. The formation of the visible precipitate in the test zone occurs when the test urine is negative for the drug. When the drug is present in the urine, no band is observed due to competition between the drug in the specimen with drug in the test region of the membrane. Therefore, absence of the color band on the test region indicates a positive result. Thus, the eScreen system and the predicate devices are substantially equivalent.

6. Nonclinical Studies

Analysis of the analytical sensitivity, stability, precision, and specificity (interference with defined cross-reactive substances) were conducted using human urine specimens spiked with known concentrations of the drugs/metabolites of interest. These human urine samples were prepared from pools of certified negative urine. Certified negative urine pools were screened by immunoassay (Emit, Syva (Dade Behring) and assayed by GC/MS). Positive urine materials were prepared from certified negative urine, spiked with known concentrations of pure drug and drug metabolites. Positive urine stock solutions were verified by analysis using GC/MS. In each of these nonclinical tests, the eScreen system was shown to reproducibly detect the presence of the indicated drugs of abuse at the cutoff concentrations specified above.

7. Clinical Data

The eScreen device (eScreen Cup and eScreen Reader) is intended to provide preliminary analytical test results for Cannabinoids, Cocaine Metabolite, PCP (Phencyclidine), Opiates (Morphine) and Amphetamine (Methamphetamine) at the SAMHSA (NIDA) published cutoff concentrations. The clinical human urine samples were aliquots obtained from SAMSHA certified laboratories that had been previously screened by Emit and confirmed by GC/MS in accordance with the guidelines established for SAMSHA certified laboratories.

The comparison between the results obtained with the eScreen Device using clinical samples previously screened by Emit and confirmed by GC/MS demonstrated that the eScreen Device provides an accurate preliminary test result (91% agreement of eScreen system to GC/MS).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

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eScreen Inc.
c/o: Jonathan S. Kahan
Hogan and Hartson L.L.P.
555 Thirteenth Street N. W.
Washington, D.C. 20004

Re: K003352
Trade Name: eScreen Drugs of Abuse Screening System
Regulatory Class: II
Product Code: LAF, DIO, DJG, LDJ, LCM
Dated: March 5, 2001
Received: March 6, 2001

Dear Mr. Kahan:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(K) Number (if known): K003352

Device Name: eScreen Drugs of Abuse Screening System

Indications for Use:

The eScreen Drugs of Abuse Screening System is intended for use by professionals in prescription workplace settings for the rapid, qualitative detection of target drugs and/or metabolites, including cocaine, cannabinoids, methamphetamine, opiates, and phencyclidine, in urine. It is intended for use by professionals for the automated screening of drugs of abuse in human urine and is not intended for over the counter sales to lay persons.

Jean Cooper

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K003352

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____
(Optional Format 1-2-96)